REMARKS

I. Claim Rejections and Amendments

Claims 1-17 are pending in the present Application. The Information Disclosure Statements have been object to; Claims 1, 2, 3, 4, 6, 9, 10, and 15-17 have been rejected under 35 U.S.C. 112, second paragraph, as indefinite; Claims 1-17 have been rejected under 35 U.S.C. 112, first paragraph, as non-enabling; Claims 1-2, 10-11, and 15-16 have been rejected under 35 U.S.C. 102(b) as being anticipated by Florio, US 5,840,715; Claims 1-2, 10-11, and 14-16 have been rejected under 35 U.S.C. 102(b) as being anticipated by www.dhea.com/jointrec.htm; Claims 1-2, 10-11, and 15-16 have been rejected under 35 U.S.C. 102(b) as being anticipated by Henderson, US 6,255,295; Claims 1-5 and 10-17 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Florio US 5,840,715 taken with Henderson et al US 6,255,293(5) and www.dhea.com/jointrec.htm and Myers US 6,911,215 B2; Claim 6-9 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Florio US 5,840,715 taken with Henderson et al US 6,255,295 and www.dhea.com/jointrec.htm in view of Myers US 6,911,215 B2 as applied to claims 1-5 and 10-17; Claims 1-17 have been rejected under the judically created doctrine of obviousness-type double patenting as unpatentable over Claims 1-20 of co-pending US Patent Application No. 11/199,359; and Claims 1-17 have been rejected under the judically created doctrine of obviousness-type double patenting as unpatentable over Claims 1-33 of co-pending US Patent Application No. 10/774,951.

The Claims have been amended in this Response to obviate rejections by the Examiner and improve the wording in the Claims. Support for the amendments is found throughout the Application, including language in the Claims and in Paragraphs on page 2, lines 14 through 24. No new matter has been added. Upon entry of these amendments, Claim 1-17 will remain pending in the Application. Reexamination and reconsideration of the Application as amended are respectfully requested.

II. IDS

The Examiner states that the International Search Report (ISR) for PCTIUS2005100424 and written opinion (WO) PCTIUS2005100424 filed in the

Information Disclosure Statements (IDS) filed on December 13, 2004 and August 10 2005 were not considered because neither are a publication. A careful review of the ISR, WO, and the IDS shows that all the references cited in the ISR and WO are cited in the IDS. The ISR and WO were apparently included for completeness. No further disclosure is required.

III. Rejections Under 35 U.S.C. § 112, Second Paragraph

The First Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 1, 3, 6, 10, and 15-17 have been rejected under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. The claim is considered indefinite as to what are or are not cartilage abnormalities. This rejection is respectfully traversed.

The Examiner states that "[I]s it the cartilage formation that is abnormal or is it the components in the cartilage that are abnormal? How does administering the claimed combination of a sulfur containing amino acid compound and manganese treat the abnormalities or the cartilage, the claim is unclear as to the measure of 'decreasing cartilage abnormality'." The Examiner's questions and statements are misplaced. What constitutes "cartilage abnormalities" is well known to skilled artisans and would therefore not be considered indefinite. See, *Ex parte Moelands*, 3 U.S.P.Q.2d 1474 (Bd. Pat. App. Int. 1987) (claims are not indefinite if the metes and bounds of the subject matter of the claims could readily be determined by one of ordinary skill in the art). For example, the publication entitled "*American Journal of Neuroradiology*" (26:674-678, March 2005) illustrates the state of the art and demonstrates that "cartilage abnormalities" is a term well known to skilled artisans. The reference is based upon a study of cartilage abnormalities using preoperative CT in various sinus cancers. The reference seeks to determine if such abnormalities were predictive of local outcome after partial laryngectomy. The reference simply refers to "cartilage abnormalities" and leaves it to the reader, a skilled artisan, to understand what cartilage abnormalities are. Similarly, a measure of "decreased cartilage abnormality" would simply be a lessening

of the severity of or a disappearance of the abnormality. All such definitions are well within the knowledge of the skilled artisan.

Further, cartilage abnormalities are well defined and characterized in the Specification. Page 1, lines 14-24 and Page 3, lines 1-5 clearly define cartilage abnormalities that are well known to skilled artisans.

It is well settled that a claim is not indefinite if it is precise when read in light of the Specification. See, *In re Sneed and Young*, 218 U.S.P.Q. 385 (C.A.F.C. 1983) and *In re Mattison et al.*, 184 U.S.P.Q. 484 (C.C.P.A. 1975). The Specification clearly defines cartilage abnormalities and what is required to decrease such cartilage abnormalities.

The question regarding how the combination of sulfur containing amino acid compound and manganese treat the abnormalities or the cartilage is again misplaced and appears to be an enablement and not an indefiniteness requirement. However, it is clear that an applicant is not required to understand or explain the mechanism of action of the invention under either standard. See, *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570, 219 U.S.P.Q. 1137, 1140 (Fed. Cir. 1983) (an inventor "need not comprehend the scientific principles on which the practical effectiveness of his invention rests").

Therefore, read in light of the Specification and given the knowledge of the skilled artisan, the claims as written would be clear to the skilled artisan and thus are not indefinite. The rejection under 35 U.S.C. §112, second paragraph, is therefore improper and should be withdrawn.

The Second Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 1, 3, 6, 10, and 15-17 have been rejected under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. The claim is considered indefinite because the term "at least" is not defined in the Claims or the Specification. This rejection is respectfully traversed.

The requirements of §112 are satisfied if the disclosure reasonably apprises the ordinary artisan, in light of what is well-known in the art, how to make and how to use a claimed invention throughout its scope. In the present Application, the term "at least" means one or more than one of the sulfur-containing amino acids. There are only

a few sulfur-containing amino acids to select from and they are well known to skilled artisans, e.g., cysteine and methionine. Further, it is well settled that a claim is not indefinite if it is precise when read in light of the Specification. See, *In re Sneed and Young*, 218 U.S.P.Q. 385 (C.A.F.C. 1983) and *In re Mattison et al.*, 184 U.S.P.Q. 484 (C.C.P.A. 1975). The Specification clearly defines the sulfur-containing amino acids on Page 4, lines 4-10 of the Specification.

Therefore, read in light of the Specification and given the knowledge of the skilled artisan as to the identity and limited scope of sulfur-containing amino acids, the claims as written would be clear to the skilled artisan and thus are not indefinite. The rejection under 35 U.S.C. §112, second paragraph, is therefore improper and should be withdrawn.

The Third Rejection under 35 U.S.C. § 112, Second Paragraph

Claim 2 has been rejected under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. The claim is considered indefinite because the "animal is prevented from having the disease but yet the Claim requires selecting the disease to be treated." Claim 2 has been amended to obviate this rejection.

The Fourth Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 4 and 9 has been rejected under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. The claim is considered indefinite because the 1.2 weight percent is unclear. Claims 4 and 9 have been amended to obviate this rejection. Support for the amendment is found on Page 4, lines 15-21 in the Specification.

The Fifth Rejection under 35 U.S.C. § 112, Second Paragraph

Claim 6 has been rejected under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. The claim is considered indefinite as to what are or are not cartilage abnormalities. This rejection is respectfully traversed.

Again, the Examiner's questions and statements are misplaced. What constitutes "cartilage abnormalities" is well known to skilled artisans and would therefore not be considered indefinite. See, *Ex parte Moelands*, 3 U.S.P.Q.2d 1474 (Bd. Pat. App. Int. 1987) (claims are not indefinite if the metes and bounds of the subject matter of the claims could readily be determined by one of ordinary skill in the art). For example, the publication entitled "*American Journal of Neuroradiology*" (26:674-678, March 2005) illustrates the state of the art and demonstrates that "cartilage abnormalities" is a term well known to skilled artisans. The reference is based upon a study of cartilage abnormalities using preoperative CT in various sinus cancers. The reference seeks to determine if such abnormalities were predictive of local outcome after partial laryngectomy. The reference simply refers to "cartilage abnormalities" and leaves it to the reader, a skilled artisan, to understand what cartilage abnormalities are. Similarly, a measure of "decreased cartilage abnormality" would simply be a lessening of the severity of or a disappearance of the abnormality. All such definitions are well within the knowledge of the skilled artisan.

Further, cartilage abnormalities are well defined and characterized in the Specification. Page 1, lines 14-24 and Page 3, lines 1-5 clearly define cartilage abnormalities that are well known to skilled artisans.

It is well settled that a claim is not indefinite if it is precise when read in light of the Specification. See, *In re Sneed and Young*, 218 U.S.P.Q. 385 (C.A.F.C. 1983) and *In re Mattison et al.*, 184 U.S.P.Q. 484 (C.C.P.A. 1975). The Specification clearly defines cartilage abnormalities and what is required to treat such cartilage abnormalities.

The question regarding how the combination of sulfur containing amino acid compound and manganese treat the abnormalities or the cartilage is again misplaced and appears to be an enablement and not an indefiniteness requirement. However, it is clear that an applicant is not required to understand or explain the mechanism of action of the invention under either standard. See, *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570, 219 U.S.P.Q. 1137, 1140 (Fed. Cir. 1983) (an inventor "need not comprehend the scientific principles on which the practical effectiveness of his invention rests").

Therefore, read in light of the Specification and given the knowledge of the skilled artisan, the claims as written would be clear to the skilled artisan and thus are

not indefinite. The rejection under 35 U.S.C. §112, second paragraph, is therefore improper and should be withdrawn.

IV. Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-17 have been rejected under 35 U.S.C. 112, first paragraph, as non-enabling because the Specification, while being enabling for treating the diseases, does not reasonably provide enablement for preventing or decreasing cartilage abnormalities with all compounds containing sulfur amino acid and manganese. This rejection is respectfully traversed.

Applicants' Specification is presumably enabling for what it discloses. An assertion by the Examiner that the Specification is not enabling for the protection sought in the Claims must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Applicants submit that no such evidence or reasoning has been advanced by the Examiner. The mere assertion that the Specification is not sufficient and a recitation of the Wand factors is insufficient to overcome the presumption of enablement granted to Applicant.

Referring to the Examiner's assertions, the nature of the present invention is, as stated above, well known to skilled artisans. As shown by the publication cited herein, cartilage types and their abnormalities are common knowledge to skilled artisans.

The Examiner asserts as a mere conclusion that there "is no one particular decreasing cartilage abnormalities is effective for all forms of cartilage abnormalities" and attempts to solve the problem by offering the Examiner's own solution, e.g., physical activity and good nutrition. The deaconess and WebMD references cited by the Examiner are illustrative of the prior art. However, an assertion in the prior art that teaches away from the present invention cannot be properly used by the Examiner to preclude patentability of a new invention based upon the statements in the prior art and the Examiners acceptance of such statements as a means to preclude all future advancements in the art.

Further, the Examiner concludes that the state of the art is unpredictable and requires *in vitro* and *in vivo* screening for patentability of the present invention. However, the Specification provides several examples to demonstrate the invention.

The examples show results from experiments with pigs. Also, the number of sulfur-containing amino acids is very few, as shown on Page 4, lines 4-11 of the Specification and as well known to skilled artisans. Applicant is not seeking to claim a genus with "hundreds" of members. Similarly, cartilage diseases are limited to a few diseases, all well known to the skilled artisan and clearly defined in the Specification. The Examiner merely sets fourth conclusions without evidence to support the conclusions. The Examiner must produce sufficient evidence that one of ordinary skill in the art would have reason to doubt the claimed utility of the invention and not rely on references that merely questioned the state of the art or the accuracy of methods for treating the disease. See, *In re Brana*, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995).

While it is true that governmental agencies, e.g., the FDA, may require extensive testing before a product can be marketed, the same is not true for patents. The courts have pointed out that while a government agency may require extensive human testing of a compound before it will grant approval for its use in medical treatments, the statutory requirements for a patent only require statistically significant tests with standard experimental animals in order to establish utility. *In re Brana*. Therefore, the experiments with pigs are sufficient to support Applicant's invention.

The Examiner asserts that undue experimentation would be required to use the invention. As stated, there are a limited number of sulfur-containing amino acids and only one manganese. Similarly, there are a limited number of well known and understood cartilage abnormalities. Further, the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation "must not be unduly extensive." *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. *Ex parte Jackson*, 217 USPQ 804, 807 (1982). Factors to consider when determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or

absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir 1988). All of the factors need not be reviewed when determining whether a disclosure is enabling. *See Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts."). Given the teaching in the Specification, the limited number of possible combinations, and the knowledge of the art, no undue experimentation would be required to use the present invention.

Contrary to the Examiner's assertions, there are three (3) working examples in the Application. See Page 6.

Therefore, read in light of the Specification and given the knowledge of the skilled artisan, the claims as written would be enabled to the skilled artisan and thus are not indefinite. The rejection under 35 U.S.C. §112, second paragraph, is therefore improper and should be withdrawn.

V. Rejections Under 35 U.S.C. § 102(b)

The First 35 U.S.C. § 102(b) Rejection

Claims 1-2, 10-11, and 15-16 have been rejected under 35 U.S.C. 102(b) as being anticipated by Florio, US 5,840,715. This rejection is respectfully traversed.

Anticipation under 35 U.S.C. §102 is a technical rejection that must meet strict standards; there is no anticipation unless all of the same elements or their equivalents are found in exactly the same situation and united in the same way to perform an identical function in a single prior art reference. *RCA Corp. v. Applied Digital Data Sys., Inc.*, 730 F.2d 1440, 221 U.S.P.Q. 385 (Fed. Cir.) cert dismissed, 468 U.S. 1228 (1984) (the claimed invention must be identically disclosed in a single prior art reference in order to be unpatentable). See also, *Rite-Nail Packaging Corp. v. Berryfast, Inc.*, 219 U.S.P.Q. 104 (CA 9 1983). See also, *Studiengesellschaft Kohle, m.b.H. v. Dart Industries, Inc.*, 220 U.S.P.Q. 841, 842 (C.A.F.C. 1984) (It is hornbook law that anticipation must be found in a single reference, device or process). The single reference must describe and enable the

claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons of ordinary skill in the field of the invention. *Crown Operations International, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375, 62 USPQ2d 1917, 1921 (Fed. Cir. 2002).

The Examiner states that "Florio discloses S-adenosyl-methionine (a sulfur-containing amino acid) (see col. 3 lines and manganese (see abstract) to treat osteoarthritis and provides relief from arthritis as in Claims 1-2, 10-11 and 15-16. Treating, enhancing and preventing as recited in the above Claims are anticipated because the end result is to relieve the patient thereof of the symptoms. If an animal is anticipated, as animals are the only ones capable of suffering from joint pains/arthritis."

Florio discloses daily nutritional supplements useful for treating arthritis. The supplements contain (a) gamma linolenic acid (unrefined), hereinafter "GLA"; (b) a mixture of eicosapentaenoic acid an docosahexaneoic acid, hereinafter collectively "EPA"; (c) a mixture of chondroitin sulfate, N-acetyl glucosamine sulfate, glucosamine sulfate and manganese aspartate. Contrary to the Examiner's assertions, the reference does not disclose using sulfur-containing amino acids for the prevention or treatment of arthritis. The reference discloses only that the "essential amino acid methionine, administered as S-adenosyl-methionine, was shown to be superior to ibuprofen (Motrin) in the treatment osteoarthritis in a double-blind clinical trial. The positive effect in this trial is consistent with several other clinical studies. Methionine is a sulfur-containing amino acid which is very important in cartilage structures, especially proteoglycans and glycosaminoglycans." This language is in the "Background of the Invention" and refers to prior art studies. The cited reference essentially list this study as one of many that have been tried and met with limited success. The reference then goes on to state that the problems with this study (and others) are solved by the present invention; the supplement containing a combination of ingredients as listed in the abstract and claims.

Further, it is unclear what the role of manganese is in the cited reference. It is an element of something referred to as CHONDROX. Even assuming that the manganese is used in the formulation in a manner similar to the present invention, it is clear that it

is not used in combination with sulfur-containing amino acids since sulfur-containing amino acids are not part of the formulation taught by the reference.

In contrast, the present invention is a method for improving cartilage abnormalities and preventing cartilage degradation using a combination of at least one sulfur-containing amino acid and manganese. The sulfur-containing amino acids are an integral part of the invention, not a problem in the prior art to be overcome. The sulfur-containing amino acids and manganese are used in combination, without the GLA, EPA, and mixture of ingredients (only one of which contains manganese) taught by the reference.

Further, the invention claimed in Claims 11 directs the invention toward many different conditions other that arthritis. The cited reference is directed to arthritis only. Clearly, there is nothing in the cited reference that discloses these other conditions.

Contrary to the Examiner's conclusion, the elements of Florio and the present invention are not the same nor are they used in the same way to perform an identical function. The rejection under 35 U.S.C. §102(b) is therefore improper and should be withdrawn.

The Second 35 U.S.C. § 102(b) Rejection

Claims 1-2, 10-11, and 14-16 have been rejected under 35 U.S.C. 102(b) as being anticipated by www.dhea.com/jointrec.htm (1998). This rejection is respectfully traversed.

The Examiner states that "www.dhea.com/jointrec.htm discloses as in current claims 1-2, 10-11, and 15-16, a composition for the treatment of arthritis, dl-methionine and manganese. Treating, enhancing and preventing as recited in the above claims are anticipated because the end result is to relieve the patient thereof of the symptoms. If an animal is anticipated, as animals are the only ones capable of suffering from joint pains/arthritis. Oral administration is anticipated as the composition is in a form of a tablet."

The cited web site is a commercial web site that sells and promotes numerous supplements for the prevention and treatment of many different diseases. However, there is nothing on the web site that specifically discloses the use of sulfur-containing amino acids in combination with manganese for the prevention or treatment of

cartilage abnormalities. There is certainly nothing on the web site that discloses that the combination is useful for companion animals.

In contrast, the present invention is a method for improving cartilage abnormalities and preventing cartilage degradation using a combination of at least one sulfur-containing amino acid and manganese.

Therefore, contrary to the Examiner's conclusion, the elements of the web site and the present invention are not the same nor are they used in the same way to perform an identical function. The rejection under 35 U.S.C. §102(b) is therefore improper and should be withdrawn.

The Third 35 U.S.C. § 102(b) Rejection

Claims 1-2, 10-11, and 15-16 have been rejected under 35 U.S.C. 102(b) as being anticipated by Henderson, US 6,255,295. This rejection is respectfully traversed.

The Examiner states that "[H]enderson et al teach administering a composition for reducing inflammation of connective tissue in animals by administering orally (see col. 20 lines 50+) S-adenosylmethionine an amino sugar that contains manganese (see col. 10 lines 45-65+) as in claims 1-2, 10-11 and 15-16. Treating, enhancing and preventing as recited in the above claims are anticipated because the end result is to relieve the patient thereof of the symptoms."

Henderson teaches using at least two compounds selected from S-Adenosylmethionine (SAM), an aminosugar selected from the group consisting of glucosamine, glucosamine salts, glucosamine hydrochloride, galactosamine, N-acetylglucosamine, and fragments, mixtures or salts thereof, and a glycosaminoglycan or glycosaminoglycan-like compound selected from the group consisting of chondroitin, chondroitin salts, hyaluronic acid, glucuronic acid, iduronic acid, keratan sulfate, keratin sulfate, heparan sulfate, dermatin sulfate, PPS, sodium PPS, calcium PPS, oversulfated GAGs, and fragments, salts, and mixtures thereof. Henderson teaches that manganese may be optionally included.

Clearly, all of the same elements or their equivalents are found in exactly the same situation and united in the same way to perform an identical function in the cited reference. The reference teaches using at least two compounds that do not include manganese. The present invention claims using a combination of at least one sulfur-

containing amino acid and manganese. Therefore, contrary to the Examiner's conclusion, the elements of the reference and the present invention are not the same nor are they used in the same way to perform an identical function. The rejection under 35 U.S.C. §102(b) is therefore improper and should be withdrawn.

VI. The Rejections Under 35 U.S.C. § 103(a)

The Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 U.S.P.Q. 459, 467 (1966) set forth the test for determining obviousness under 35 U.S.C. §103(a). Determining obviousness requires four kinds of factual inquiries:

(1) the scope and content of the prior art;
(2) the differences between the prior art and the claimed invention;
(3) the level of ordinary skill in the field of the invention; and
(4) any objective indicia of success such as commercial success, long felt need, and copying.

See also, Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH, 139 F.3d 877, 881, 45 U.S.P.Q.2d 1977 (Fed. Cir. 1998).

The proper standards for making determinations under 35 U.S.C. §103 were reiterated in *In re Kahn*, 441 F.3d 977 (Fed. Cir. 2006). First, the court determines the scope and content of the prior art, and ascertains the differences between the prior art and the claims at issue, and resolves the level of ordinary skill in the pertinent art. Against this background, the court determines whether the subject matter would have been obvious to a person of ordinary skill in the art at the time of the asserted invention. In *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 872, 228 U.S.P.Q. 90, 98 (Fed. Cir. 1985) the Federal Circuit elaborated:

> In patent cases, the need for express Graham findings takes on an especially significant role because of an occasional tendency of district courts to depart from the Graham test, and from the statutory standard of obviousness that it helps determine, to the tempting but forbidden zone of hindsight.

Further, to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the teachings in the references. In addition, the references when combined must teach or suggest all the claim limitations. *See* MPEP §2143. In addition,

obviousness must be reviewed from the perspective of one skilled in the art at the time of the invention without the benefit of hindsight. *Tyco Indus. v. Tiny Love, Ltd.*, 914 F. Supp. 1068, 1079 (D.N.J. 1996). The combination of two or more references is "hindsight" where "express" motivation is lacking. *See* MPEP §2145. Thus, there must be a teaching or suggestion within the prior art, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor. *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546, 48 USPQ 1321, 1329 (Fed. Cir. 1998). Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. *Id.*

Further, a prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *See In re Gurley*, 27 F.3d 551, 553, 31 U.S.P.Q.2d 1130, 1131 (Fed. Cir. 1994).

The First 35 U.S.C. § 103(a) Rejection

Claims 1-5 and 10-17 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Florio US 5,840,715 taken with Henderson et al US 6,255,293(5) and www.dhea.com/jointrec.htm and Myers US 6,911,215 B2. This rejection is respectfully traversed.

The Examiner reviewed the disclosure in the cited references and concluded that "[O\]ne of ordinary skill in the art would have been motivated to combine the above teaching and employ in the treatment of decreasing cartilage abnormalities in animals." The Examine further states that "[A]ll of the critical elements in the instant claims are taught by combining the above cited references and would have been successful in doing so." However, careful review of the references shows that there is nothing in the references to motivate a skilled artisan to combine the references to achieve the present invention and that the references cannot be combined to achieve the present invention. Further, careful review of the cited references shows that only thorough selective culling components from the prior art by picking and choosing

from various elements of the cited references that correspond to elements of the present invention and the mistaken use of impermissible hindsight can the Examiner mistakenly conclude that the references can be combined to achieve the present invention.

Claims 1-5 and 10-17 are directed to methods for improving cartilage abnormalities and preventing cartilage degradation and to compositions suitable for decreasing cartilage abnormalities or preventing cartilage degradation using a combination of at least one sulfur-containing amino acid and manganese.

Florio discloses daily nutritional supplements useful for treating arthritis. The supplements contain (a) gamma linolenic acid (unrefined), hereinafter "GLA"; (b) a mixture of eicosapentaenoic acid an docosahexaneoic acid, hereinafter collectively "EPA"; (c) a mixture of chondroitin sulfate, N-acetyl glucosamine sulfate, glucosamine sulfate and manganese aspartate. Florio does not disclose the use sulfur-containing amino acids for the prevention or treatment of arthritis. Florio mentions that the essential amino acid methionine, administered as S-adenosyl-methionine, was shown to be superior to other compounds (ibuprofen) for the treatment of osteoarthritis. However, this is in the prior art section of the reference. Florio goes on to identify past treatments, such as the use of methionine, as problems that need to be solved. Then, Florio teaches that the combination of (a), (b) and (c) above solves those problems. Essentially, Florio teaches that sulfur-containing amino acids were used ineffectively in the prior art and asserts that Florio's invention solves the problems with the prior art methods. In contrast, the present invention claims using a combination of at least one sulfur-containing amino acid and manganese to manage cartilage abnormalities. The present invention, contrary to Florio's teachings, uses the sulfur-containing amino acids in a manner that Florio deems a problem with the prior art.

Similarly, Florio tangentially discloses the use of manganese in a formulation that contains numerous ingredients. Nothing in the reference discloses using manganese in combination with sulfur-containing amino acids for any purpose. The present invention, however, is directed to a combination of manganese and at least one sulfur-containing amino acid wherein the manganese is one of the critical elements of the invention.

There is nothing in Florio that would motivate a skilled artisan to combine the reference with other references to achieve the present invention. Not only is there nothing to motivate a combination of Florio with other references, Florio in essence teaches away from the present invention. Florio teaches that sulfur-containing amino acids are ineffective for treating arthritis and that the nutritional supplements of Florio are required to combat arthritis. Certainly a skilled artisan would not be motivated to use prior art methods cited by Florio as ineffective to develop compositions and methods for managing cartilage abnormalities.

Henderson teaches using at least two compounds selected from S-Adenosylmethionine (SAM), an aminosugar selected from the group consisting of glucosamine, glucosamine salts, glucosamine hydrochloride, galactosamine, N-acetylglucosamine, and fragments, mixtures or salts thereof, and a glycosaminoglycan or glycosaminoglycan-like compound selected from the group consisting of chondroitin, chondroitin salts, hyaluronic acid, glucuronic acid, iduronic acid, keratan sulfate, keratin sulfate, heparan sulfate, dermatin sulfate, PPS, sodium PPS, calcium PPS, oversulfated GAGs, and fragments, salts, and mixtures thereof. Henderson teaches that manganese may be optionally included. There is nothing in Henderson that would motivate a skilled artisan to combine the reference with other references to achieve the present invention. Henderson requires three ingredients - SAM, an aminosugar, and glycosaminoglycan or glycosaminoglycan-like compound. A skilled artisan reading Henderson would conclude that mixtures of several different compounds are required to manage the condition. Nothing would motivate such an artisan to simplify the composition to two simple compounds, i.e., the sulfur-containing amino acid and manganese of the present invention. Certainly a skilled artisan would not be motivated to use the Henderson compositions and methods to develop compositions and methods for managing cartilage abnormalities. There is no teaching or suggestion in Henderson to motivate a skilled artisan to look to particular sources of information, to select particular elements, and to combine them in the way they were combined in the present invention.

www.dhea.com/jointrec.htm is a commercial web site that sells and promotes numerous supplements for the prevention and treatment of many different diseases. However, there is nothing on the web site that specifically discloses the use of sulfur-

containing amino acids in combination with manganese for the prevention or treatment of cartilage abnormalities. The Arthriticure® JointRecovery® Next Generation product sold on the web site does not contain sulfur-containing amino acids. There is certainly nothing on the web site that would motivate a skilled artisan to combine the teaching on the web site with other references to achieve the present invention. The web site essentially teaches that all diseases can be cured by the vitamins and minerals sold on the web site, in any combination. A skilled artisan would simply look at this web site as commercial "puffing" designed to entice customers and would not be motivated to use its teachings to develop new methods for managing cartridge abnormalities.

Myers teaches a biscuit having an arthritis-treating combination, namely glucosamine sulfate, vitamin C and an array of intracellular ions, namely potassium, sodium and iodine. Myers does not teach using sulfur-containing amino acid and manganese to affect cartilage abnormalities. Further, there is nothing to motivate a skilled artisan to combine Myers with other references to achieve the present invention. Basically, Myers teaches using biscuits to deliver arthritis-treating drugs or drug combinations. Myers does not motivate a skilled artisan to look for new methods and compositions to affect cartridge abnormalities. At best, Myers motivates one to look for new and better delivery systems for such compositions.

Importantly, only the impermissible use of hindsight would permit the Examiner to pick and choose from the teachings in the cited references to achieve the present invention. Only after learning from the present Specification that sulfur-containing amino acids and manganese can be used to affect cartilage abnormality and cartilage degradation can the Examiner read the references, pick and choose from various elements of the references, and conclude that the references can be combined to achieve the present invention. Absent the teaching of the present invention, a skilled artisan could not conclude that sulfur-containing amino acids and manganese could be used to affect cartridge. Further, given the Examiner' reasoning, the skilled artisan would conclude that simple methods would be unsuccessful and that mixtures of many different types of compounds would be required to achieve the present invention. This basically teaches away from Applicant's invention by encouraging

skilled artisans to use many different compounds rather than the two claimed in the present invention.

In conclusion, there is nothing in the cited references to motivate a skilled artisan to combine references teaching (1) GLA, EPA, and mixtures of various compounds, (2) SAM, amino sugars, and glycosaminoglycan compounds, and (3) using biscuits do deliver medications to achieve the present invention. In fact, the cited references cannot be combined to achieve the present invention and it is only through hindsight that the Examiner could mistakenly believe that the cited references could be combined to achieve the present invention. Therefore, a prima facie case of obviousness cannot be established.

Therefore, using the *Graham* test, it can clearly be seen that the rejected Claims are not obvious in view of the cited references. The difference between the present invention and the prior art as disclosed in the cited references is so dramatic that the cited references could not be combined to achieve the present invention. There is certainly nothing in the cited references to provide a teaching that would motivate a skilled artisan to combine them to achieve the present invention. In fact, the cited references teach away from the present invention and only hindsight would permit the invention to be deemed obvious. The rejection under 35 U.S.C. §103(a) is therefore improper and should be withdrawn.

The Second 35 U.S.C. § 103(a) Rejection

Claim 6-9 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Florio US 5,840,715 taken with Henderson et al US 6,255,295 and www.dhea.com/jointrec.htm in view of Myers US 6,911,215 B2 as applied to Claims 1-5 and 10-17. This rejection is respectfully traversed.

The Examiner reviewed the disclosure in the cited references and concluded that [O\]ne of ordinary skill in the art would have been motivated to combine the above teaching and employ in the treatment of decreasing cartilage abnormalities in animals. All of the critical elements in the instant claims are taught by combining the above cited references and would have been successful in doing so." The Examine further states that "[T]he claimed subject matter is not patentably distinct over the aabove cited prior art of record." However, careful review of the references shows that

there is nothing in the references to motivate a skilled artisan to combine the references to achieve the present invention and that the references cannot be combined to achieve the present invention. Further, careful review of the cited references shows that only thorough selective culling components from the prior art by picking and choosing from various elements of the cited references that correspond to elements of the present invention and the mistaken use of impermissible hindsight can the Examiner mistakenly conclude that the references can be combined to achieve the present invention.

Claims 6-9 are directed to compositions suitable for decreasing cartilage abnormalities in an animal comprising a cartilage abnormality decreasing effective amount of a combination of at least one sulfur-containing amino acid and manganese and a carrier.

Florio discloses daily nutritional supplements useful for treating arthritis. The supplements contain (a) gamma linolenic acid (unrefined), hereinafter "GLA"; (b) a mixture of eicosapentaenoic acid an docosahexaneoic acid, hereinafter collectively "EPA"; (c) a mixture of chondroitin sulfate, N-acetyl glucosamine sulfate, glucosamine sulfate and manganese aspartate. Florio also discloses the use of manganese in a formulation that contains numerous ingredients. Nothing in the reference discloses compositions containing manganese in combination with sulfur-containing amino acids. The present invention, however, is directed to a combination of manganese and at least one sulfur-containing amino acid and a carrier. Florio mentions that the essential amino acid methionine, administered as S-adenosyl-methionine, was shown to be superior to other compounds (ibuprofen) for the treatment of osteoarthritis. However, this is in the prior art section of the reference and the compound was apparently used alone and not in a composition comprising a combination with manganese. Florio goes on to identify past treatments, such as the use of methionine, as problems that need to be solved. Then, Florio teaches that the combination of (a), (b) and (c) above solves those problems. Essentially, Florio teaches that sulfur-containing amino acids were used ineffectively in the prior art and asserts that Florio's invention solves the problems with the prior art compositions. In contrast, the present invention claims a composition comprising a combination of at least one sulfur-containing amino acid and manganese to manage cartilage abnormalities. The present invention,

contrary to Florio's teachings, uses the sulfur-containing amino acids in a manner that Florio deems a problem with the prior art and uses the compounds in a composition that requires both compounds.

There is nothing in Florio that would motivate a skilled artisan to combine the reference with other references to achieve the present composition. Not only is there nothing to motivate a combination of Florio with other references, Florio in essence teaches away from the present invention. Florio teaches that sulfur-containing amino acids are used alone and are ineffective for treating arthritis and that the nutritional supplement compositions of Florio are required to combat arthritis. Certainly a skilled artisan would not be motivated to use prior art compositions cited by Florio as ineffective to develop compositions and methods for managing cartilage abnormalities.

Henderson teaches a composition having at least two compounds selected from S-Adenosylmethionine (SAM), an aminosugar selected from the group consisting of glucosamine, glucosamine salts, glucosamine hydrochloride, galactosamine, N-acetylglucosamine, and fragments, mixtures or salts thereof, and a glycosaminoglycan or glycosaminoglycan-like compound selected from the group consisting of chondroitin, chondroitin salts, hyaluronic acid, glucuronic acid, iduronic acid, keratan sulfate, keratin sulfate, heparan sulfate, dermatin sulfate, PPS, sodium PPS, calcium PPS, oversulfated GAGs, and fragments, salts, and mixtures thereof. Henderson teaches that manganese may be optionally included in the composition. However, there is nothing in Henderson that would motivate a skilled artisan to combine the reference with other references to achieve the present composition. Henderson requires three ingredients - SAM, an aminosugar, and glycosaminoglycan or glycosaminoglycan-like compound. A skilled artisan reading Henderson would conclude that mixtures of several different compounds are required and would not conclude that only sulfur-containing amino acids and manganese would be included in the composition. In fact, Henderson teaches that at least two of the compounds other than manganese must be included in the composition. Nothing would motivate such an artisan to simplify the composition to two simple compounds, i.e., the sulfur-containing amino acid and manganese of the present invention. Certainly a skilled artisan would not be motivated to use the Henderson compositions and methods to develop compositions and methods for managing cartilage abnormalities. There is no

teaching or suggestion in Henderson to motivate a skilled artisan to look to particular sources of information, to select particular elements, and to combine them in the way they were combined in the present invention.

www.dhea.com/jointrec.htm is a commercial web site that sells and promotes numerous supplements for the prevention and treatment of many different diseases. However, there is nothing on the web site that specifically discloses the use of sulfur-containing amino acids in combination with manganese for the prevention or treatment of cartilage abnormalities. The Arthriticure® JointRecovery® Next Generation product sold on the web site does not contain sulfur-containing amino acids. There is certainly nothing on the web site that would motivate a skilled artisan to combine the teaching on the web site with other references to achieve the present invention. The web site essentially teaches that all diseases can be cured by the vitamins and minerals sold on the web site, in any combination. A skilled artisan would simply look at this web site as commercial "puffing" designed to entice customers and would not be motivated to use its teachings to develop new methods for managing cartridge abnormalities.

Myers teaches a biscuit composition having an arthritis-treating combination, namely glucosamine sulfate, vitamin C and an array of intracellular ions, namely potassium, sodium and iodine as its components. Myers does not teach using sulfur-containing amino acid and manganese to affect cartilage abnormalities. Further, there is nothing to motivate a skilled artisan to combine Myers with other references to achieve the present composition. Basically, Myers teaches using biscuits to deliver arthritis-treating drugs or drug combinations. Myers does not motivate a skilled artisan to look for new methods and compositions to affect cartridge abnormalities. At best, Myers motivates one to look for new and better delivery systems for such compositions.

Only the impermissible use of hindsight would permit the Examiner to pick and choose from the teachings in the cited references to achieve the present composition. Only after learning from the present Specification that sulfur-containing amino acids and manganese can be used to affect cartilage abnormality and cartilage degradation can the Examiner read the references, pick and choose from various elements of the references, and conclude that the references can be combined to achieve the present

invention. Absent the teaching of the present invention, a skilled artisan could not conclude that a composition containing sulfur-containing amino acids and manganese is disclosed in the prior art.

In conclusion, there is nothing in the cited references to motivate a skilled artisan to combine references teaching (1) GLA, EPA, and mixtures of various compounds, (2) SAM, amino sugars, and glycosaminoglycan compounds, and (3) using biscuits do deliver medications to achieve the present composition. In fact, the cited references cannot be combined to achieve the present invention and it is only through hindsight that the Examiner could mistakenly believe that the cited references could be combined to achieve the present invention. Therefore, a prima facie case of obviousness cannot be established.

Therefore, using the *Graham* test, it can clearly be seen that the rejected Claims are not obvious in view of the cited references. The difference between the present invention and the prior art as disclosed in the cited references is so dramatic that the cited references could not be combined to achieve the present invention. There is certainly nothing in the cited references to provide a teaching that would motivate a skilled artisan to combine them to achieve the present invention. In fact, the cited references teach away from the present invention and only hindsight would permit the invention to be deemed obvious. The rejection under 35 U.S.C. §103(a) is therefore improper and should be withdrawn.

VII. Response to the Double Patenting Rejections

Claims 1-17 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-20 of co-pending US Patent Application No. 11/199,350 and Claims 1-17 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-33 of co-pending US Patent Application No. 10/774,951. A terminal disclaimer (to the extent necessary) will be filed once the claims in this Application have been found to be otherwise allowable.

VIII. Conclusion

In summary, the objection to the IDS; the rejections under 35 U.S.C. §102, §103, and §112; and the Double Patenting rejection has been obviated or overcome. In view of the foregoing Remarks, it is submitted that the Claims are in condition for allowance. Reexamination and reconsideration of the Application are requested and allowance of the Claims at an early date is solicited.

If the Examiner believes that personal communication will expedite prosecution of this Application, the Examiner is invited to call the undersigned at the number listed below.

Respectfully submitted,

Friesen *et al.*

/Wendell Ray Guffey/

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By: Wendell Ray Guffey
Reg. No.: 31,762
Hill's Pet Nutrition, Inc.
Capital Tower Building
400 SW 8th Avenue
Topeka, KS 66603
Telephone: (785) 286-8285

WRG/dlh